

Rob Seidman, Pharm.D., M.P.H. Vice President Blue Cross of California Pharmacy

2510 'S9 MAY -4 MO:03

April 30,1999

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-21)
ATTN: Gloria Ortega
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Ortega:

In support of FDA docket number 98P-0610/CP, we have recently obtained copies of reported adverse drug events for over-the-counter non-sedating antihistamines available in Canada. A search of the entire Canadian national database was performed for all suspected adverse events associated with over-the-counter non-sedating antihistamines. All information provided is current from each drug's date of initial marketing through April 12, 1999. The Continuing assessment Division of the Bureau of Drug Surveillance in Canada provided the reports. It is important to note that the reports provided to the Bureau have not been scientifically or otherwise verified as to the cause and effect relationship between the drugs taken and their potential negative impact on the patient.

Of the million of over-the-counter antihistamine doses dispensed in Canada, the Canadian Bureau of Drug Surveillance received 79 potential incidents of a drug interaction for fexofenadine, 94 for loratadine and 43 for cetirizine. In the majority of these cases where a suspected adverse drug reaction occurred, the patient recovered without any impairment. In all cases, the relationship between the drug and the reported adverse event could not be established.

In support of docket number 98P-0610/CP, I request that the FDA review the over-the-counter safety data compiled by the Canadian Bureau of Drug Surveillance. In addition, please review the safety data in the direct to over-the-counter Canadian drug approvals for loratedine, fexofenadine and cetirizine.

Thank you,

Robert Seidman

cc: Andrea Masciale

98P-0610

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Health Santé Canada Canada



APR 13 '99 14:31 FR B DRUG SURVEILLANCE

Part I: 23 pages + this one Part II: 19 pages + this one Part III: 19 pages + this one

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TO/À:

Robert Seidman

FAX: 1(818) 712-6482 TEL: (818) 610-4817 DATE: April 13, 1999

NUMBER OF PAGES TO FOLLOW: 61 NOMBRE DE PAGES À SUIVRE:

#### MESSAGE/MESSAGE:

Dear Mr. Seidman,

This is further to your fax dated December 16, 1998 requesting information on suspected adverse drug reactions (ADRs) associated with the use of cetirizine, fexofenadine and loratedine. We apologize for the delay.

A search of the national database was performed for all the suspected adverse reactions associated with these suspected drugs. The attached printouts outline the results. These printouts cover the time period since marketing until April 12, 1999. There may be reports which have been received by the program which are not yet entered into the database. Kindly direct your attention of all persons using these printouts to the following Caveat:

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Protection Branch is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Protection Branch scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization.

If you have any further questions, please do not hesitate to contact me.

Case report number	Drug _name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0066744		64 Year(s)	Funiale					Recovered without sequelae
	LORATA	DINE			02 Month(s)	Suspected	10.00 Milligrams 1 Daily	
	Sys	tem Organ Cl	ass:			WHO Advers	e Reaction Term:	
				DNAL DISORD	ERS	WEIGHT IN	CREASE	
	CALCIUN	1 SUPPLEM	ENT			Concomitant	500.0 Milligrams 3 Daily	
	VITAMIN	C				Concomitant	500.0 Milligrams i Daily	
	VITAMIN	E				Concomitant	400.0 Milligrams 1 Daily	
0067394		57 Year(s)	Malc			_		Recovered without sequelac
	CLARITI				08 Day(s)	Suspected	10.00 Milligrams 1 Daily	
		tem Organ Cli					e Reaction Term:	
		/CHIATRIC I				AGITATION		-
4		· · · · · · · · · · · · · · · · ·		RAL DISORDE	RS		CTOID REACTION	The Control of the Co
		CHIATRIC I				ANOREXIA		
				EM DISORDER	(S	DYSPHAGIA		
1981		ION DISORI				VISION BLU		<del>-</del>
			SYSTEM DIS	OKDERS		DYSPNOEA		
		CHIATRIC I		OVOTEM DIO	An Debe	IRRITABILI FAINTNESS		
			'H NEKVOUS	SYSTEM DISC	JKDEKS	Other	10.00 Milligrams 1 Daity	
	HISMAN							•
	SELDANI	;				Other	60.00 Milligrams 2 Daily	· .
0068518		30 Year(s)	Female					Recovered without sequelac
	CLARITI				02 Day(s)	Suspected	10.00 Milligrams 1 Daily	
		tem Organ Cl					e Reaction Term:	
			LETAL SYST	EM DISORDE	RS	MYALGIA		
	AMITRIP	TYLINE				Concomitant	50.00 Milligrams 1 Daily	
0069857		63 Year(s)	Female					Recovered without sequelae
	CLARITI					Suspected	10.00 Milligrams	
	•	tem Organ Cl				WHO Adverse		
			DISORDERS			NIGHTMAR		
	CHOLED	YL				Concomitant	100.0 Milligrams	

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April 12, 1999

SURVEILLANCE

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0070678		40 Year(s)	Male					Recovered without sequelac
	CLARITIN	Ī				Suspected	1.00 Dosage form	
	Syste	em Organ Clas	is:			WHO Advers	e Reaction Term:	
0070943	PSY	CHIATRIC D	ISORDERS			LIBIDO DEC	CREASED	
0070843		74 Year(s)	Male					Recovered without sequelae
	CLARITIN				01 Day(s)	Suspected	10.00 Milligrams	
		em Organ Clas				WHO Advers	e Reaction Term:	
	HEA	.RT RATE AN	ND RHYTHM	DISORDERS		TACHYCAR	RDIA ATRIAL	
)	METAMU	CIL				Concomitant	10.00 Millicurie 2 Daily	
0073162		40 Year(s)	Female					Recovered without sequelac
0075102	CLARITIN					Suspected	,	
	Syste	em Organ Clas	s:			WHO Advers	e Reaction Term;	
				DISORDERS		TACHYCAR	RDIA	
		•		C) DISORDER:	S	FLUSHING		
	VISI	ON DISORDI	ERS			ACCOMMO	DATION ABNORMAL	
0073942		36 Year(s)	Male					Recovered without sequelac
	CLARITIN				01 Day(s)	Suspected	10.00 Milligrams	
		m Organ Clas					e Reaction Term:	•
		CHIATRIC DI				INSOMNIA		·
	HEA	RT RATE AN	ID RHYTHM	DISORDERS		TACHYCAR		<i>.</i> ••
	ORUDIS				02 Day(s)	Concomitant	200.0 Milligrams	
	PENGLOB	E			04 Day(s)	Concomitant	400.0 Milligrams 2 Daily	

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Case report	Drug A	ge	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome			
0074381	70 Y	'ear(s)	Female					Recovered without sequelse			
	CLARITIN				01 Day(s)	Suspected	1.00 Dosage form 1 Daily				
	System (	Organ Clas	s:			WHO Advers	e Reaction Term:				
	SKIN A	ND APPEI	NDAGES D	ISORDERS		RASH ERYT	HEMATOUS				
	CENTR	& PERIPI	I NERVOU	S SYSTEM DISC	ORDERS	DIZZINESS					
	BODY A	AS A WHO	LE - GENE	RAL DISORDE	RS	OEDEMA O	FEXTREMITIES				
	MUSCU	LO-SKEL	ETAL SYS	TEM DISORDER	RS .	JOINT SWEI	LLING NON-INFLAMM	ATORY			
	SKIN A	ND APPEI	NDAGES D	ISORDERS		PRURITUS					
	PREMARIN					Concomitant					
	PREDNISONE	:				Treatment	30.00 Milligrams				
0076929		ear(s)	Female					Not yet recovered			
	CLARITIN				03 Day(s)	Suspected	•				
		Organ Clas					10.00 Milligrams Reaction Term:				
				ONAL DISORDI	ERS	WHO Adverse Reaction Term: DEHYDRATION					
		DISORDE			_	EYE ABNOR					
nd.		O-INTEST	INAL SYST	TEM DISORDER		MOUTH DR'					
	CENTRUM				13 Day(s)	Concomitant	1.00 Dosage form				
	ESTROGENS				Continuing on Drug	Concomitant	1.00 Dosage form				
	TEA				01 Week(s)	Concomitant					
078195		ear(s)	Female			······································		·			
	CLARITIN					Suspected	10.00 Milligrams 2 Daily				
		Irgan Clas.			_		e Reaction Term:				
				RAL DISORDE	RS	CHEST DISC	COMFORT				
			SORDERS			ANOREXIA					
				S SYSTEM DISC		DIZZINESS					
				RAL DISORDER		MALAISE					
			INAL SYST	EM DISORDER	S	NAUSEA					
079176		ear(s)	Female		04.0			Recovered without sequelae			
	CLARITIN				04 Day(s)	Suspected					
		Organ Clas.	s: SORDERS				Reaction Term:				
	BPS Y CFII	ATRICIDI	SOKDEKS			INSOMNIA					

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0079581		41 Year(s)	Female					Recovered without sequelac
	CLARITIN	4				Suspected	1.00 Dosage form	,
	Syst	em Organ Cla	iss:			WHO Advers	e Reaction Term:	
		CHIATRIC I				PERSONALI	ITY DISORDER	
	VENTOLI	N				Concomitant		
0081473		40 Year(s)	Female					Recovered without sequelae
	CLARITIN					Suspected	1.00 Dosage form	
		em Organ Cla					e Reaction Term:	
			ENDAGES DIS			PRURITUS		
			ENDAGES DIS	ORDERS		URTICARIA	•	
		INT INHALE				Concomitant		
		N FOR INHA	LATION			Concomitant	12	
	HYDROC	ORTISONE				Treatment		
0081772		60 Year(s)	Male			_		Recovered without sequelae
	CLARITIN				04 Day(s)	Suspected	10.00 Milligrams	
	•	em Organ Cla		D/440DDDD4			e Reaction Term:	
	, HEA	ART RATE A	ND RHYTHM	DISORDERS		TACHYCAR	DIA	
0081773		36 Year(s)	Male					Recovered without sequelae
	CLARITIN					Suspected	10.00 Milligrams 2 Daily	
		em Organ Cla					e Reaction Term:	.*
			EM DISORDE		_	URINARY R		
		STRO-INTES	TINAL SYSTE	M DISORDER	S	MOUTH DR		
	LOPID					Concomitant	1200 Milligrams	
0081875		45 Year(s)	Female					
	CLARITIN					Suspected	1.00 Dosage form	
		em Organ Cla				WHO Advers		
			ND RHYTHM	DISORDERS		PALPITATIO		
	CONJUGA	TED ESTRO	OGENS			Concomitant	0.62 Milligrams 1 Daily	

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#### Summary of Reported Adverse Drug Reactions Active Ingredient: Loratadine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0081975		29 Year(s)	Female					Recovered without sequel ne
	CLARIT					Suspected	10.00 Milligrams   Daily	
		stem Organ Cla					e Reaction Term:	
	CE	ENTR & PERIF	PH NERVOUS	SYSTEM DISC	ORDERS	PARAESTHI	ESIA	
0082427		-	Female					Recovered without sequelae
	CLARIT	IN			01 Day(s)	Suspected	1.00 Dosage form 1 Daily	•
	Sy	stem Organ Cla	25 <i>5</i> ;			WHO Advers	e Reaction Term:	
	G/	ASTRO-INTES	TINAL SYSTI	EM DISORDEI	<b>US</b>	NAUSEA		
	CE	ENTR & PERIF	PH NERVOUS	SYSTEM DISC	ORDERS	HEADACHE		
			H NERVOUS			DIZZINESS		
			IOLE - GENER	AL DISORDE	RS	CHILLS		
	NOVOSP	IROTON				Concomitant	100.0 Milligrams As necess	ary
	RIVOTR	IL				Concomitant	0.50 Milligrams 2 Daily	
0082533		52 Year(s)	Male					Recovered without sequelac
p-	CLARIT	IN .				Suspected	10.00 Milligrams 1 Daily	•
_	Sy	stem Organ Cla	រា.ខ.			WHO Adverse	Reaction Term;	
•	G.A	ASTRO-INTES	TINAL SYSTE	EM DISORDEI	RS	ABDOMINA	L PAIN	
0082534		45 Year(s)	Female					Recovered without sequelae
-	CLARITI	N				Suspected	10.00 Milligrams	•
	Sy:	stem Organ Cla	.cz.:			WHO Adverse	Reaction Term:	<i>.</i> •
	G/	STRO-INTES	TINAL SYSTE	EM DISORDE	RS	DYSPEPSIA		
	ZANTAC					Treatment	150.0 Milligrams	
0083443		47 Year(s)	Female					Recovered without sequelae
	CLARITI				05 Month(s)	Suspected	10.00 Milligrams	
		stem Organ Cla					Reaction Term:	
			ND RHYTHM			TACHYCAR		
			OLE - GENER	AL DISORDE	RS		AGGRAVATED	
	ISOPTIN					Other	240.0 Milligrams	
	VERAPA	MIL HYDRO	CHLORIDE I			Treatment		

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Case report	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0083826		38 Year(s)	Male					Recovered without sequelae
	CLARIT	IN				Suspected	t0.00 Milligrams	
		stem Organ Cle				WHO Advers	e Reaction Term:	
		EART RATE A		•		ARRHYTHM		
	H	EART RATE A	ND RHYTHM	DISORDERS		PALPITATIO	ON	
0083845		7 Year(s)	Male					Recovered without sequelac
	CLARIT	'IN			01 Day(s)	Suspected	5.00 Milligrams	·
	S)	stem Organ Cla	iss:			WHO Advers	e Reaction Term:	
	P	LATELET,BLE	EDING & CLO	OTTING DISOR	RDERS	<b>EPISTAXIS</b>		
0084067		41 Year(s)	Male					Recovered without sequelae
	CLARIT	IN			01 Day(s)	Suspected	10.00 Milligrams 1 Daily	
		vstein Organ Cla					e Reaction Term:	
		SYCHIATRICI				HALLUCINA	ATION	
				SYSTEM DISC	ORDERS	DIZZINESS		
		ORT INHALE	CR			Concomitant	As necessary	
		HYLLINE				Concomitant	600.0 Milligrams	
	VENTO	LIN				Concomitant	As necessary	
0084068	<del></del>	45 Year(s)	Male					
	CLARIT				01 Day(s)	Suspected	10.00 Milligrams 1 Daily	
	•	stem Organ Cla					e Reaction Term:	.•
		ESPIRATORY				DYSPNOEA		
				RAL DISORDE		CHEST PAIN		
				ERS, GENERA		OEDEMA D	•	
	Be		OLE - GENER	RAL DISORDE	<i>\$</i> 2	ALLERGIC I	REACTION	
0084069		29 Year(s)	Female			, , , , , , , , , , , , , , , , , , ,		Recovered without sequelae
	CLARIT				01 Day(s)	Suspected	10.00 Milligrams	
	-	stem Organ Cla				WHO Adverse		
	C	entr & Perip	H NERVOUS	SYSTEM DISC	ORDERS	PARAESTH	ESIA	

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# 끘 13 199 14:33 FR Œ. DRUG SURVEILLANCE

#### Summary of Reported Adverse Drug Reactions Active Ingredient: Loratadine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
084070		48 Year(s)	Female					Not yet recovered
	CLARIT				05 Year(s)	Suspected		
	•	vstem Organ Cl				WHO Advers	e Reaction Term:	
	С	ENTR & PERI	PH NERVOUS	SYSTEM DISC	ORDERS	PARAESTH	ESIA	
0084071		42 Year(s)	Female		<del></del>			Not yet recovered
	CLARIT	'IN			10 Day(s)	Suspected	10.00 Milligrams	
	S	stem Organ Cl	ass:			WIIO Advers	e Reaction Term:	
	P	SYCHIATRIC	DISORDERS			PARONIRIA		
	BECON.	ASE				Concomitant	2.00 Dosage form 2 Daily	
	PREMA	RIN				Concomitant	0.62 Milligrams	
0084080		24 Year(s)	Male					Recovered without sequelae
	CLARIT	'IN		•••	01 Day(s)	Suspected	1.00 Dosage form	
		istem Organ Cl				WHO Advers	e Reaction Term;	
		SYCHIATRIC:				HALLUCINA		
		SYCHIATRIC				DROWSINE	SS	
	В	ODY AS A WI	IOLE - GENER	AL DISORDE	RS	FATIGUE		
0084116		49 Year(s)	Male	·	<u></u>		<del></del>	Recovered without sequelae
		IN EXTRA			02 Day(s)	Suspected	5.00 Milligrams 2 Daily	,
		stem Organ Cl					e Reaction Term:	· ,*
			ND RHYTHM			PALPITATIO		÷
			ILAR DISORDI	ERS, GENERA	L	HYPERTENS	NOIS	
	VASOTI	EC .				Trestment		
0084118		•	Male					Recovered without sequelae
	CLARIT					Suspected	10.00 Milligrams	
		stem Organ Cl					e Reaction Term:	
	M	ETABOLIC A	ND NUTRITIO	NAL DISORDI	ERS	OEDEMA PE	ERIORBITAL	
0084191		44 Year(s)	Male					Recovered without sequelae
		IN EXTRA			02 Day(s)	Suspected	1.00 Dosage form	
		stem Organ Cl			N. G.	WHO Adverse		
	₩ M	IUSCULO-SKE	LETAL SYSTE	M DISORDER	<b>IS</b>	ARTHRALG	IA	

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0084372		7 Year(s)	Female					Recovered without sequelac
	CLARITIN				01 Day(s)	Suspected	10.00 Milligrams	•
		ın Organ Cl				WHO Advers	e Reaction Term:	
				SYSTEM DISC	ORDERS	SHAKING		
	HEA	RT RATE A	ND RHYTHM	DISORDERS		ARRHYTHN	ΛΙΑ	
0084373		5 Year(s)			<del></del>			Recovered without sequelar
	CLARITIN				01 Day(s)	Suspected	10.00 Milligrams 2 Daily	-
		m Organ Cl				WHO Advers	e Reaction Term:	
			DISORDERS			EUPHORIA		
			DISORDERS				ITY DISORDER	
	CEN	TR & PERII	PH NERVOUS	SYSTEM DISC	ORDERS	TREMOR LI	MB	
0084374		Year(s)	Female	····				Not yet recovered
	CLARITIN				01 Day(s)	Suspected	1.00 Teaspoonful	
		m Organ Cl					e Reaction Term:	
			DISORDERS			SLEEP DISC		
	ROBITUSS	IN-DM			09 Day(s)	Concomitant	1.00 Teaspoonful	
0084477	•		Female					Recovered without sequelac
	CLARITIN					Suspected	10.00 Milligrams 1 Daily	
		m Organ Cle			_		e Reaction Term:	* •
				EM DISORDER			L DISCOMFORT	$\cdot$
	GAS	IRO-INTES	STINAL SYSTI	EM DISORDER	.S	DIARRHOEA	4	
0084478	-		Female			_		Recovered without sequelac
	CLARITIN					Suspected	10.00 Milligrams I Daily	
		m Organ Cle		/ DYGGE	. ca		e Reaction Term:	
	GAS	I RO-INTES	TINAL SYSTI	EM DISORDER	S	ABDOMINA	L DISCOMFORT	4
0085161		8 Year(s)	Female					Recovered without sequelac
	CLARITIN				01 Day(s)	Suspected	5.00 Milligrams	
	•	m Organ Clo			•		e Reaction Term:	
			ENDAGES DIS		_	SWEATING		
				EM DISORDER	S	ABDOMINA	L PAIN	
	PSYC	JHIATRIC I	DISORDERS			ANOREXIA		

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Case report number	Drug game	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome		
0085651		76 Year(s)	Female			***************************************				
<u> </u>	CLARITI	ν				Suspected	1.00 Dosage form   Daily			
j	Sys	lem Organ Cla	75S:			WHO Advers	e Reaction Term:			
<u> </u>	ВО	DY AS A WI	OLE - GENER	RAL DISORDE	RS	CHEST TIGI				
0085839		54 Year(s)	Male					Recovered without sequelac		
	CLARITI	Y				Suspected	10.00 Milligrams			
) ]	Sysi	em Organ Cla	N. R			WHO Advers	e Reaction Term:			
)	UR	INARY SYST	EM DISORDE	ers		URINARY RETENTION				
	HYTRIN					Concomitant				
0086074		24 Year(s)	Malc					Recovered without sequelae		
•	CLARITI	<b>V</b>			01 Day(s)	Suspected	10.00 Milligrams 1 Daily	The Market		
	Syst	em Organ Cla	185:							
<b>2</b>	PSY	CHIATRIC I	DISORDERS			EMOTIONA	L LABILITY			
0086445			Female					Recovered without sequelae		
	CLARITI	4			19 Day(s)	Suspected	1.00 Dosage form 1 Daily			
	Syst	em Organ Cla	<b>s</b> s:			WHO Advers	e Reaction Term:			
	GA	STRO-INTES	TINAL SYSTI	EM DISORDER	<b>RS</b>	DYSPEPSIA				
4	CE	vtr & perip	H NERVOUS	SYSTEM DISC	DRDERS	PARAESTHI	ESIA			
•	GA:	STRO-INTES	TINAL SYSTI	EM DISORDER	S.	NAUSEA	.•			

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Case report	Drug A	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0086756		Year(s)	Male					Died drug may be contributory	
	CLARITIN				13 Day(s)	Suspected	10.00 Milligrams Daily		
		Organ Cla				WHO Advers	e Reaction Term:		
	GAST	RO-INTES	TINAL SYST	EM DISORDER	RS	VOMITING			
	BODY	AS A WH	OLE - GENE	RAL DISORDE	RS	MALAISE			
	BODY	AS A WH	OLE - GENE	RAL DISORDE	RS	WEAKNESS	GENERALIZED		
	PLATE	LET,BLE	EDING & CL	OTTING DISOI	RDERS	EMBOLISM	MESENTERIC		
	RESPI	RATORY	SYSTEM DIS	ORDERS		PULMONAR	RY HAEMORRHAGE		
	PSYCH	HATRIC E	DISORDERS			SEDATION			
	URINA	RY SYST	EM DISORD	ERS		RENAL FAII	LURE ACUTE		
	LIVER	AND BIL	IARY SYSTE	M DISORDERS	3	HEPATIC FA	AILURE		
				M DISORDERS		BUDD CHIA	ARI SYNDROME		
				EM DISORDER	lS .	EPIGASTRIC	C PAIN NOT FOOD-REI	LATED	
				1 DISORDERS		CARDIAC A	RREST		
				SYSTEM DISC		ENCEPHALO			
				M DISORDERS		HEPATIC NI	ECROSIS		
				DERS, GENERA		HYPERTENS			
•		•		OTTING DISOR			IBIN TIME PROLONGE	D	
			EDING & CL	OTTING DISOF	RDERS	THROMBOO			
	NEOPL						OBIN INCREASED	· ·	
				1 DISORDERS		TACHYCAR		· .	
				M DISORDERS	3	HEPATOME			
			SYSTEM DIS				RY RATE INCREASED		
				M DISORDERS			USIVE LIVER DISEASI	3	
			ID NUTRITIC	DNAL DISORDI	ERS	DEHYDRAT	ION		
	CHEMOTHE	RAPY				Treatment			
0086781		Year(s)	Male					Recovered without sequelae	
	CLARITIN					Suspected	10.00 Milligrams As nece	SSRry	
	•	Organ Cla	ss:			WHO Adverse Reaction Term:			
	NEOPL	ASM				CARCINOM	A		

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# TO 18187126482

#### Summary of Reported Adverse Drug Reactions Active Ingredient: Loratadine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

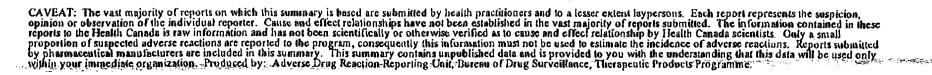
Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0086791		45 Year(s)	Male					Recovered without sequelae
0086791	CLARIT					Suspected	1.00 Dosage form 1 Daily	
		stem Organ Cla				WHO Advers	se Reaction Term:	
	HE	EART RATE A	NHYTHA DK	M DISORDERS		PALPITATI	ON	
<del>0086960</del>		20 Year(s)	Male					Recovered without sequelac
	CLARITI	N				Suspected	30.00 Milligrams   Daily	
	Sys	stem Organ Cla	2SS.			WHO Advers	se Reaction Term:	
	SK	IN AND APPI	ENDAGES DI	SORDERS		RASH		
) )	PREDNIS	ONE				Treatment		
2087080		41 Year(s)	Male					Recovered without sequelae
	CLARITI	N				Suspected	,	w.
	Sys	stem Organ Cla	uss:			WHO Advers	se Reaction Term:	•
	PS	YCHIATRIC I	DISORDERS			IMPOTENC	E	
	REPRODUCTIVE DISORDERS, MALE					EJACULAT	ION FAILURE	
0087092		38 Year(s)	Male	·				Recovered without sequelae
	CLARITI				03 Month(s)	Suspecied	10.00 Milligrams   Daily	
		tem Organ Cla				WHO Advers	se Reaction Term:	
	RE	SPIRATORY	SYSTEM DIS	ORDERS		DYSPNOEA	•	· .
0087095		4 Year(s)	Female					Recovered without sequelac
	CLARITI	N				Suspected	5.00 Milligrams 1 Daily	•
	Sys	tem Organ Cla	zs <i>s:</i>			WHO Advers	se Reaction Term:	
	BC	DY AS A WH	OLE - GENE	RAL DISORDE	RS	ALLERGIC	REACTION	
	BC	DY AS A WH	OLE - GENE	RAL DISORDEI	RS	OEDEMA	•	
	SK	IN AND APPE	ENDAGES DI	SORDERS		SKIN DISOI	RDER	
	MULTIP	LE VITAMIN	S			Concomitant	1.00 Dosage form	
	NOVAMO	MIXC				Concomitant	1000 Milligrams	
	BENADR	YL .				Trentment	25.00 Milligrams	
	EPINEPH	RINE AERO	SOL			Treatment		
	*							
	<b>T</b>							

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0087320		-	Female					Recovered without sequel ac	
	CLARITI	N			02 Day(s)	Suspected	10.00 Milligrams	•	
	Sys	tem Organ C	Class:			WHO Advers	e Reaction Term:		
	SK	IN AND AP	PENDAGES DI	SORDERS		RASH			
	ВО	DY AS A W	HOLE - GENE	RÁL DISORDE	RS	THERAPEU	TIC RESPONSE DECP	REASED	
	BENADR	YL				Treatment	50.00 Milligrams		
3087354		20 Year(s)	Malc					Recovered without sequelae	
	CLARITI	N EXTRA				Suspected	1.00 Dosage form 2 Da	aily	
5	Sys	tem Organ C	lass:			WHO Advers	e Reaction Term:		
	PS	YCHIATRIC	DISORDERS			ANXIETY			
<b>.</b>	GA	STRO-INTE	STINAL SYST	EM DISORDE	lS .	NAUSEA			
1087470	<del></del>	28 Year(s)	Female					Recovered without sequelae	
<b>}</b> .	CLARITI				01 Day(s)	Suspected	1.00 Dosage form 1 Dr	aily	
		tem Organ C				WHO Advers	e Reaction Term:		
				DERS, GENERA		OEDEMA D	EPENDENT		
				EM DISORDEF		ARTHRALG	IA .		
			-	RAL DISORDE		CHEST DISC			
				SYSTEM DISC	ORDERS	PARAESTHI	ESIA		
			SYSTEM DIS			RESPIRATO	RY DISORDER	·.·	
	CEI	NTR & PER	IPH NERVOUS	SYSTEM DISC		STUPOR		•	
	ERYBID				06 Day(s)	Concomitant	1.00 Dosage form As n	ecessary	
0087699	· · · · · · · · · · · · · · · · · · ·	•	Male					Not yet recovered	
	CLARITI					Suspected	10.00 Milligrams		
	_	tem Organ C				WHO Adverse Reaction Term:			
	SKI	IN AND API	PENDAGES DI	SORDERS		DERMATITI	S EXFOLIATIVE		



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#### Active Ingredient: Loratadine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

Case report	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0087756		Year(s)	Female					Recovered without sequelac
	CLARITIN					Suspected	250.0 Milligrams 3 Daily	
		n Organ Cl					e Reaction Term:	
			SYSTEM DIS	•		BRONCHOS	SPASM	
			ENDAGES DIS			PRURITUS		
			ENDAGES DIS	SORDERS		RASH		
	BENADRYL					Concomitant		
}	ATARAX					Treatment	50.00 Milligrams As necess	зму
)	SOLU-COR	ref				Treatment	250.0 Milligrams	
0088174		Yeau(s)	Male					Recovered without sequelac
•	CLARITIN				06 Day(s)	Suspected	10.00 Milligrams   Daily	
		ı Organ Cl				WHO Advers	e Reaction Term:	· ·
				EM DISORDER		SALIVA INC	CREASED	
-				EM DISORDER	KS .	DYSPHAGIA	A	
	PSYC	HIATRIC	DISORDERS			DISORIENT	ATION	
0088175	•		Female					Recovered without sequelac
	<b>CLARITIN I</b>				01 Day(3)	Suspected	1.00 Dosage form 2 Daily	
	•	i Organ Cl				WHO Advers	e Reaction Term:	
			SYSTEM DISC			SINUSITIS		
	PLAT	ELET,BLE	EDING & CLO	TTING DISOF	RDERS	PURPURA		
0088185		Year(s)	Female	····				Recovered without sequelae
	CLARITIN				Ol Day(s)	Suspected	80.00 Milligrams 1 Daily	
		ı Organ Cl				WHO Advers	e Reaction Term:	
	CENT	R & PERII	PH NERVOUS	SYSTEM DISC	ORDERS	DIZZINESS		
0088270		Year(s)	Female					Not yet recovered
	CLARITIN					Suspected	2.00 Dosage form 1 Daily	
	•	Organ Cl					e Reaction Term:	
			ES OTHER, DI		· <u>.</u>	SMELL ALT		
	SPECI	AL SENS	es other, di	SORDERS		TASTE LOS	S	
		<del></del>						

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome			
116434		19 Year(s)	Female					Unknown			
	CLARIT					Suspected					
	_	vstem Organ Cla					e Reaction Term:				
	R	EPRODUCTIV	E DISORDERS	, FEMALE		LABOUR PR	REMATURE				
116436		•			<del></del>			Died drug may be contributory			
	CLARIT	'IN				Suspected					
	S)	vstem Organ Cla	7SS.			WHO Advers	e Reaction Term:				
	N	EONATAL AN	D INFANCY D	DISORDERS		BIRTH PREI	MATURE				
	F	DETAL DISOR	DERS			CONGENITA	AL ANOMALY NOS				
116751		-	Female					Recovered without sequelae			
	CLARIT	IN EXTRA				Suspected	First dose	·= ,			
	S)	istem Organ Cla	15S:	v	·	WHO Advers	e Reaction Term:	•			
	SI	KIN AND APPI	ENDAGES DIS	ORDERS		<b>ERYTHEMA</b>	1				
	SI	KIN AND APPI	ENDAGES DIS	ORDERS		PRURITUS					
	B	ODY AS A WH	OLE - GENER	AL DISORDE	RS	OEDEMA O	F EXTREMITIES				
	V	ASCULAR (EX	TRACARDIA	C) DISORDER:	S	FLUSHING					
	Н	EART RATE A	ND RHYTHM	DISORDERS		PALPITATIO	NC				
116753		-	Male				<u> </u>	Recovered without sequelae			
	CLARIT	IN				Suspected	10 Milligrams Daily	$\cdot$			
	Sy	stem Organ Cla	iss.			WHO Adverse Reaction Term:					
	B	ODY AS A WH	OLE - GENER	AL DISORDE	RS	CHEST PAIN	4				

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#### Active Ingredient: Loratadine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome		
116763	BJAXIN Sys	71 Year(s) stein Organ Cla	Female			Suspected WHO Advanced	250 Milligrams 2 Daily	Recovered without sequelae		
	HE CLARITI Sys	CART RATE A N Stem Organ Cla	ND RHYTHM 33:	DISORDERS  DISORDERS		WHO Adverse Reaction Term: TACHYCARDIA SUPRAVENTRICULAR Suspected I Dosage form Daily WHO Adverse Reaction Term:				
	APO-ENA BIQUIN I LOSEC ADENOS	LAPRIL DURULES	ND KHY I HW	IDISOKDEKS	Continuing on Drug Continuing on Drug Continuing on Drug	TACHYCAR Concomitant Concomitant Concomitant Treatment	DIA SUPRAVENTRICU 5 Milligrams Daily 250 Milligrams 3 Daily 20 Milligrams Daily	JLAR		
116764	CLARITI	II Year(s) N EXTRA	Female	•	2 Day(s)	Suspected	I Dosage form Daily	Recovered without sequelae		
	CA PSY HE	(CHIATRIC D ART RATE AN DY AS A WHO	.AR DISORD ISORDERS ND RHYTHM	ERS, GENERAI DISORDERS RAL DISORDER		WHO Adverse HYPERTENS CATATONIC TACHYCARI SYNCOPE	e Reaction Term: SION CREACTION			
	OTRIVIN					Concomitant Concomitant				
116770		- N Iem Organ Clas ART RATE AN		DISORDERS			Reaction Term: DIA VENTRICULAR	Unknown		

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#### All Reports received and entered into database before April 12, 1999

Case repoi	d Drug Latue	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116830		80 Year(s)	Female					Unknown
	CLARIT				~2 Month(s)	Suspected	10 Milligrams As necessary	
		stem Organ Cl				WHO Advers	e Reaction Term:	
		ESPIRATORY				PNEUMONI	A	
				M DISORDERS		TORSADE D	E POINTES	
		ESPIRATORY				HYPOXAEM	IIA	
				ONAL DISORDI		HYPOKALA	EMIA	
				ONAL DISORDI		HYPONATR	AEMIA	
	М	ETABOLIC A	ND NUTRITI	ONAL DISORDI	ERS	HYPERGLY	CAEMIA	
	ASPIRIN	CHILDREN	8			Concomitant	80 Milligrams Daily	
	BONAM	NE				Concomitant	25 Milligrams 3 Daily	
	BRICAN	YL				Concomitant	0.5 Milligrams 4 Daily	
	PACEMA	KER				Concomitant	-	
	PULMIC					Concomitant	2 Dosage form 4 Daily	
	RESTOR	IL.				Concomitant	15 Milligrams Daily	
	SYNTHR	OID				Concomitant	0.1 Milligrams Daily	
	THEO-D	UR				Concomitant	200 Milligrams 2 Daily	
	CIPRO					Other		
	ERYTHR	OMYCIN .				Other		
	FLOVEN	Т				Other		
	VENTOL	IN				Other		
	LIDOCA	INE				Treatment		•
16843		50 Year(s)	Female					Not yet recovered
	CLARITI				Continuing on Drug	Suspected	10 Milligrams Daily	
		stem Organ Cla				WHO Adverse	Reaction Term:	
				RAL DISORDEF		PAIN		
	GA	STRO-INTES	TINAL SYST	EM DISORDER	S	TOOTH ACH	IE	

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Case report number	Drug Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116844	-	Female					Recovered without sequelac
	CLARITIN EXTE	RA		6 Day(s)	Suspected	1 Dosage form Daily	
	System Org	an Class:			WHO Advers	e Reaction Term:	
	PSYCHIAT	RIC DISORDERS			DROWSINE	SS	
		RIC DISORDERS			DISORIENT	ATION	
	CENTR & 1	PERIPH NERVOUS	SYSTEM DISC	ORDERS	SLURRED S	PEECH	
	PSYCHIAT	RIC DISORDERS			HALLUCINA	ATION	
0116846	•	Female					Not yet recovered
	CLARITIN EXTR	t A		3 Day(s)	Suspected	1 Dosage form 2 Daily	
	System Orga	an Class:			WHO Advers	e Reaction Term:	
		NTESTINAL SYST			THROAT DI	<b>Υ</b>	
	CENTR & I	PERIPH NERVOUS	SYSTEM DISC	ORDERS	NUMBNESS	ORAL	
0116848	67 Year	s) Female					Not yet recovered
	CLARITIN			Continuing on Drug	Suspected		
	System Orgo	an Class:			WHO Advers	e Reaction Term:	
	GASTRO-II	NTESTINAL SYST	EM DISORDER	RS	OESOPHAG	ITIS	
	SKIN AND	APPENDAGES DIS	SORDERS		MELANOMA	A MALIGNANT	
0116882	37 Year(	s) Female				· · · · · · · · · · · · · · · · · · ·	Recovered without sequelac
	CLARITIN				Suspected	10 Milligrams First dose	•.*
	System Orgo	an Class:			WHO Advers	e Reaction Term:	.₹
	RESPIRAT	ORY SYSTEM DISC	ORDERS		BRONCHOS	PASM	
	BECLOFORTE				Concomitant		
	VENTOLIN				Concomitant		

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#### Active Ingredient: Loratadine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome		
0117178		40 Year(s)	Male					Recovered without sequelac		
	CLARIT	IN EXTRA			2 Day(s)	Suspected	1 Dosage form 2 Daily	•		
	Sy	stem Organ Cl	ass:			WHO Advers	se Reaction Term:			
	Sk	IN AND APP	ENDAGES DI	SORDERS		RASH ERY	THEMATOUS			
				S SYSTEM DISC	ORDERS	BURNING S				
		PLICATION	SITE DISORD	ERS		SKIN NECR	OSIS			
	SUDAFE					Suspected	I Dosage form 2 Daily			
	•	stem Organ Cl				WHO Advers	se Reaction Term:			
				S SYSTEM DISC	ORDERS	BURNING SKIN				
		IN AND APP				RASH ERYTHEMATOUS				
		PLICATION S	SITE DISORD	ERS		SKIN NECR	OSIS			
	PREDNI	SONE				Treatment				
0117232		47 Year(s)	Male					Recovered without sequelae		
	LORATA	DINE				Suspected	10 Milligrams Daily	•		
	-	stem Organ Cla				WHO Advers	e Reaction Term:			
				A DISORDERS		PALPITATIO	NC			
	ERYTHR	OMYCIN ET	HYLSUCCIN	₹A		Concomitant				
0117233		83 Year(s)	Female					Recovered without sequelae		
	CLARITI				4.5 Year(s)	Suspected	As necessary			
		tem Organ Cla				WHO Advers	<i>:</i>			
			ND RHYTHA	1 DISORDERS		AURICULAI				
	VENTOL				Continuing on Drug	Suspected	As necessary			
		tem Organ Cla					e Reaction Term:			
			ND KHYTHN	1 DISORDERS			R FIBRILLATION			
	COUMAI					Concomitant	I Milligrams Daily			
	LOPRES				Out to the	Concomitant	200 Milligrams Daily			
	MODURI				Continuing on Drug	Concomitant	1 Dosage form Daily			
	PREMAR				Continuing on Drug	Concomitant	0.625 Milligrams Daily			
	PROVER				O attación e a Desa	Concomitant	110.14" = "			
	SYNTHR	OID			Continuing on Drug	Concomitant	112 Micrograms Daily			
	ZOCOR				Continuing on Drug	Concomitant	10 Milligrams Daily			
	PROPAF	ENONE				Treatment				

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#### Active Ingredient: Lorafadine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

Case report	Drug Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0117491	46 Year(s)	Male					Not yet recovered
	CLARITIN EXTRA			2 Day(s)	Suspected	2 Daily	•
	System Organ (					e Reaction Term:	
		LEEDING & CL			HAEMORRE	HAGE NOS	
	COUMADIN	LEEDING & CL	OTTING DISO	RDERS	BRUISE		
	System Organ (	Class.			Suspected	7 Milligrams 1 Daily	
		c <i>iass:</i> LEEDING & CL	OTTING DIEG	bDrnc		e Reaction Term:	
		LEEDING & CL LEEDING & CL			BRUISE	TA OF NOO	
	ASPIRIN	LEDING & CE	OTTINO DISCI	NDERS	HAEMORRI Concomitant		
					Concominant	80 Milligrams 1 Daily	
117726	~	Male					Recovered without sequelac
- Can	CLARITIN	ou.			Suspected	10 Milligrams Daily	
	System Organ (	<i>Class:</i> VHOLE - GENE	DAL DICORDE	n o		Reaction Term:	
	PSYCHIATRIC		KAL DISORDE	162		URE BODY DECREASE	
		/HOLE - GENE	BAT DISORDE	DC	NERYOUSN SHIVERING		
			MAR DISORDE	NO .	DMMAYING		
117831	49 Year(s)	Female			_		Recovered without sequelae
	CLARITIN	<b>~</b> 1.		Continuing on Drug	Suspected	10 Milligrams I Daily	
	System Organ C	.iass: Y SYSTEM DIS	ODDEDE			e Reaction Term:	
		HOLE - GENE		n e	DYSPNOEA	OTO ID D.D. COMICAL	į.÷
		PENDAGES DI		u2	PRURITUS	CTOID REACTION	
	BENADRYL	I ENDAGES DE	SONDENS		Treatment		
	CORTICOSTEROID	(S)			Trestment		
	EPINEPHRINE	~/			Treatment		
110255	37 Year(s)	Male					
118355	CLARITIN EXTRA	Maic		l Month(s)	Comment A	3.D 6 D."	Recovered without sequelae
	System Organ C	Vacc-		· monunts)	Suspected WHO Ashama	2 Dosage form Daily Reaction Term:	
	Dynon Organ C	ILIBO.			WITH AGVESSE	: Reaction Term:	

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0118690		83 Year(s)	Female					Not yet recovered
	CLARITIN	1			Continuing on Drug	Suspected		
	Syste	em Organ Cla	ass:			WHO Advers	e Reaction Term:	
			ENDAGES D	ISORDERS		SKIN DISCO	LOURATION	
	<b>FLONASE</b>				Continuing on Drug	Suspected		
	Syst	em Organ Cla	485.°			WHO Advers	e Reaction Term:	
	SKI	N AND APPI	ENDAGES D	ISORDERS		SKIN DISCO	LOURATION	
	ATROVEN	VТ				Concernitant		
	BECLOFO	RTE				Concomitant		
	DIGOXIN					Concomitant		
	ENALAPR	IL.				Concomitant		
	FUROSEM	(IDE				Concomitant		**
	POTASSIU	IM CHLORI	DE			Concomitant		
118704	<u> </u>	•	Female					Not yet recovered
	CLARITIN				1-3 Month(s)	Suspected	10 Milligrams Daily	
		em Organ Cla					e Reaction Term:	
				RAL DISORDE		PAIN LEGS		
				S SYSTEM DISC		WALKING D		
		SCULO-SKE	LETAL SYS	rem disordef	<b>S</b>	MUSCLE AC	CHE	
	PROZAC					Concounitant		
	THYROID					Concomitant		
	ACUPUNC	TURE				Treatment		
19322		34 Year(s)	Female					Unknown
	CLARITIN				3 Day(s)	Suspected	10 Milligrams I Daily	
		em Organ Clo					e Reaction Term:	
	FOE	TAL DISOR	DERS			DEATH FOE	TAL	

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#### Active Ingredient: Loratedine - "Suspected Drug" All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
120082		30 Year(s)	Male					
	CLARIT				5 Day(s)	Suspected	10 Milligrams 1 Daily	
		istem Organ Cl					se Reaction Term:	
		SYCHIATRIC				irritabili		
				EM DISORDER	S	DIARRHOE		
		SYCHIATRIC				THINKING		
		SYCHIATRIC	DISORDERS			CONFUSION		
	IMODIU				Continuing on Drug	Suspected	2 Milligrams I Daily	
		istem Organ Cl					se Reaction Term:	
		SYCHIATRIC				THINKING		
		SYCHIATRIC : SYCHIATRIC :				IRRITABILI		
0120317				EM DISORDER:	c	CONFUSION		NAME OF THE PARTY
	G,			EM DISORUER	3	DIARRHOE	A	
120317		38 Year(s)	Female					Recovered without sequelae
		IN EXTRA			10 Day(s)	Suspected	t Daily	
	•	stem Organ Cl					e Reaction Term:	
•			E DISORDERS	S, FEMALE			L IRREGULARITY	
		M CARBONA			Continuing on Drug	Concomitant	Daily	
			ITH MINERA	Ĺ	Continuing on Drug	Concomitant	Daily	*_
	VITAMI	NE			Continuing on Drug	Concomitant	400 International units Daily	y
0120380		25 Year(s)	Female			<del></del>		Recovered without sequelae
	CLARIT	IN EXTRA			~S Month(s)	Suspected	2 Daily	
	. Sy	stem Organ Cla	ass:			WHO Advers	e Reaction Term:	
			E DISORDERS	S, FEMALE		BREAST PA		
	M	USCULO-SKE	LETAL SYST	EM DISORDER	S	CRAMPS		
	MULTIP	LE VITAMIN	IS			Concomitant	Daily	
	ORTHO	1/35				Concomitant	Daily	,
0120981		2 Year(s)	Female		····			Unknown
V.2070E	CLARIT					Suspected	10 Milligrams First dose	O I I I I I I I I I I I I I I I I I I I
		stem Organ Cla	ass:				e Reaction Term:	
				EM DISORDERS	\$	VOMITING		
		YCHIATRIC				DROWSINE	99	

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Case report number 0121441	Drug _name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0121441		2 Year(s)	Female					Recovered without sequelae
	CLARITIN	1				Suspected	2.5 Millilitres 2 Daily	
	Syst	em Organ C	lass:			WHO Advers	e Reaction Term:	
	PSY	'CHIATRIC	DISORDERS			LETHARGY	,	
	BOI	DY AS A W	HOLE - GENEI	RAL DISORDEI	RS	FEVER		
	GAS	STRO-INTE	STINAL SYST	EM DISORDER	S	STOMATIT	IS	
	TYLENOI	,			Continuing on Drug	Concomitant	l Teuspoonful	
0121676	TYLENOL	ELIXIR			Continuing on Drug	Concomitant	5 Millilities ~5 Daily	•
0121676	<del></del>	13 Year(s)	Male			<del></del>		Unknown
	CLARITIN	1				Suspected	15 Milligrams Daily	
	Syst	em Organ C	lass:			WHO Advers	se Reaction Term:	
er ger			AND RHYTHM	DISORDERS	4.45	QT PROLON	NGED	
*	BENADRY	(L				Concomitant		
	METHIMA	AZOLE				Concomitant	30 Milligrams 3 Daily	
	PROPRAN	OLOL HY	DROCHLORII	•		Concomitant		
0121786		•	Female					Recovered without sequelae
•	CLARITIN	1				Suspected	10 Milligrams Daily	
	Syst	em Organ C	lass:			WHO Advers	e Reaction Term:	•
	BOI	DY AS A W	HOLE - GENER	IAL DISORDE	RS	EFFICACY,	LACK OF	·:·
0121788		54 Year(s)	Female					Recovered without sequelac
	CEFTIN					Suspected	250 Milligrams 2 Daily	
		em Organ C					se Reaction Term:	
				EM DISORDER		DIARRHOE		
			STINAL SYSTI	EM DISORDER	S	CRAMP ABI		
	CLARITIN					Suspected	2 Daily	
		em Organ C		01404000	•		e Reaction Term:	
				EM DISORDER		DIARRHOE		
			STINAL SYSTI	EM DISORDER	S	CRAMP ABI	DOMINAL	
	HYDRATA					Treatment		
	METRON	IDAZOLE				Treatment		

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Case report	•	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome		
0121790		•	Male					Unknown		
	CLARITI					Suspected		•		
		stem Organ C				WHO Adver.	se Reaction Terny:			
	RE	SPIRATORY	Y SYSTEM DIS	SORDERS		THROAT IF				
			y system dis			THROAT S	ORE			
	RE	SPIRATORY	y system dis	FORDERS		COUGHING	j			
	BC	DDY AS A W	HOLE - GENE	RAL DISORDEI	RS	CONDITIO	N AGGRAVATED			
0121791		•	Female					Unknown		
	CLARITI	N				Suspected				
	Sys	stem Organ C	lass:			WHO Adverse Reaction Term:				
	BC	DY AS A W	HOLE - GENE	RAL DISORDER	RS	FEVER				
	√ GA	STRO-INTE	STINAL SYST	<b>EM DISORDER</b>	<b>S</b>	DIARRHOE	A ·			
	G/	STRO-INTE	STINAL SYST	<b>EM DISORDER</b>	S	BLOATING				
	GA	STRO-INTE	STINAL SYST	EM DISORDER	S	ABDOMINA	AL PAIN LOWER			
	M	JSCULO-SK	ELETAL SYST	TEM DISORDER	S	CRAMPS				
0121807	,	69 Year(s)	Female					Recovered without sequelae		
	CLARITI	N				Suspected	5 Milligrams 2 Daily			
	Sys	tem Organ C	lass:			WHO Advers	se Reaction Term:			
	CA	RDIOVASC	ULAR DISORI	DERS, GENERAL	L	BLOOD PRI	ESSURE HIGH	· <u>.</u>		
	ENALAP	RIL			Continuing on Drug	Concomitant	5 Milligrams Daily			
	TAMOXI	FEN			Continuing on Drug	Concomitant	20 Milligrams Daily			
	VITAMIN	IS			Continuing on Drug	Concomitant	-			
121869	<del></del>	10 Year(s)	Male			· · · · · · · · · · · · · · · · · · ·		Recovered without sequelae		
	CLARITI	N .			2 Day(s)	Suspected	10 Milligrams Daily			
	Sys	tem Organ C	lass:			•	se Reaction Term:			
	-	•	PENDAGES DI	SORDERS		RASH				

Total No. of reports 94

Total No. of reports with fatal outcome

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APR Health Canada

Health Santé Canada Canada This is - Part II: 19 pages + this one Part III: 19 pages + this one



# PRODUITS THÉRAPEUTIQUES PRODUITS THÉRAPEUTIC PRODUCTS

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> FIRST FLOOR / ler ÉTAGE OTTAWA (ONTARIO)

ADDRESS LOCATOR -0201C1 - INDICE DE L'ADRESSE

FAX: (613) 957-0335

TO/A: Robert Seidman

FAX: 1(818) 712-6482 TEL: (818) 610-4817 DATE: April 13, 1999

NUMBER OF PAGES TO FOLLOW: 61 NOMBRE DE PAGES À SUIVRE:

MESSAGE/MESSAGE:

Dear Mr. Seidman,

This is further to your fax dated December 16, 1998 requesting information on suspected adverse drug reactions (ADRs) associated with the use of cetirizine, fexofenadine and loratedine. We apologize for the delay.

A search of the national database was performed for all the suspected adverse reactions associated with these suspected drugs. The attached printouts outline the results. These printouts cover the time period since marketing until April 12, 1999. There may be reports which have been received by the program which are not yet entered into the database. Kindly direct your attention of all persons using these printouts to the following Caveat:

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If you have any further questions, please do not hesitate to contact me.

# 13 뀖 $\boldsymbol{\omega}$ SURVEILLANCE 613 957 TO 18186104817

Total No. of reports with fatal outcome

# P.02/20

## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Loratadine - "Interaction - Food" All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	<i>j</i>
O088173		•	Fentale					Not yet recovered	
E	CLARITIN	i			01 Day(s)	Interaction -Food	10.00 Milligrams   Daily	¥	
$\Theta$	Syst	em Organ C	Class:			WHO Advers	e Reaction Term:		
Ţī	CEN	ITR & PER	IPH NERVOUS	SYSTEM DIS	ORDERS	COMA			
풁	BOI	dy as a w	HOLE - GENE	RAL DISORDE	RS	ANAPHYLA	CTIC REACTION		
	FOOD RE	ACTIONS				Interaction -Food			
Ð	Syst	em Organ C	Ilass:			WHO Advers	e Reaction Term:		
.∞ .∞	CEN	NTR & PER	IPH NERVOUS	SYSTEM DIS	ORDERS	COMA			
ü	BOI	DY AS A W	HOLE - GENE	RAL DISORDE	RS	ANAPHYLA	CTIC REACTION		
H							Total No. o.	Creports 1	

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#### Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Loratadine as "Interaction drug" All Reports received and entered into database before April 12, 1999

Dosage I form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
	02 5-42		10.00 Million ( Delle	Recovered without sequelae
•	03 Day(s)	Interaction-Drug	10.00 Milligrams 1 Daily	¥!
			Reaction Term:	
JS SYSTEM DISORI		MIGRAINE		
'	Continuing on Drug	Concomitant	1.00 Dosage form 1 Daily	
			<del></del>	Recovered with sequelae
		Interaction -Drug	1.00 Dosage form   Daily	
		WHO Adverse	Reaction Term:	
AR DISORDERS		HEARING IN	<b>IPAIRED</b>	
ERAL DISORDERS		CONDITION	AGGRAVATED	
AR DISORDERS		TINNITUS		
		Interaction - Drug	1.00 Dosage form 2 Daily	No.
		WHO Adverse	Reaction Term:	
ERAL DISORDERS		CONDITION	AGGRAVATED	
ERAL DISORDERS		CONDITION	AGGRAVATED	
AR DISORDERS		TINNITUS		
ERAL DISORDERS		CONDITION	AGGRAVATED	
AR DISORDERS		TINNITUS		
AR DISORDERS		HEARING IN	<b>IPAIRED</b>	
AR DISORDERS		TINNITUS		·.•
AR DISORDERS		HEARING IN	<b>IPAIRED</b>	<i>.</i> *
AR DISORDERS		HEARING IN	<b>IPAIRED</b>	
		Interaction-Drug		
		WHO Adverse	Reaction Term:	
ERAL DISORDERS		CONDITION	AGGRAVATED	
ERAL DISORDERS		CONDITION	AGGRAVATED	
AR DISORDERS		HEARING IN	<b>IPAIRED</b>	
AR DISORDERS		HEARING IN	1PAIRED	
AR DISORDERS		TINNITUS		
AR DISORDERS		TINNITUS	·	

v is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, if feet relationships have not been established in the vast majority of reports submitted. The information contained in these en scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small rogram, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted

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Prug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

April 12, 1999

CLARITIN  System Organ Class: CENTR & PERIPH NERVOUS  OVRAL  080689  49 Year(s) Female  CLARITIN  System Organ Class: HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR	Case report number	Drug name	Age	Sex	4
CLARITIN  System Organ Class: CENTR & PERIPH NERVOUS  OVRAL  49 Year(s) Female  CLARITIN  System Organ Class: HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR	72628		25 Year(s)	Female	
OVRAL  O80689  49 Year(s) Female  CLARITIN  System Organ Class:  HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR SELDANE  System Organ Class:  BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR		CLAF	RITIN	*	
OVRAL  O80689  49 Year(s) Female  CLARITIN  System Organ Class:  HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR SELDANE  System Organ Class:  BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR	Õ				
O80689  CLARITIN  System Organ Class: HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR SELDANE  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR		• i	CENTR & PER	IPH NERVOU	SS
CLARITIN  System Organ Class:  HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR SELDANE  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR	IME	OVRA			
HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR SELDANE  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR			49 Year(s)	Female	
HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR SELDANE  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR	<del>1</del>	CLAR			
BODY AS A WHOLE - GENER HEARING AND VESTIBULAR SELDANE  System Organ Class:  BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR	. <del>70</del>				_
HEARING AND VESTIBULAR SELDANE  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR	13				
SELDANE  System Organ Class:  BODY AS A WHOLE - GENER  BODY AS A WHOLE - GENER  HEARING AND VESTIBULAR  BODY AS A WHOLE - GENER  BODY AS A WHOLE - GENER  BODY AS A WHOLE - GENER  HEARING AND VESTIBULAR  HEARING AND VESTIBULAR  HEARING AND VESTIBULAR  HEARING AND VESTIBULAR	•				
BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR	<u> </u>		HEARING AND	O VESTIBULA	XR
BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR		SELD			
BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR	424				
HEARING AND VESTIBULAR BODY AS A WHOLE - GENER HEARING AND VESTIBULAR System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR	ž				
BODY AS A WHOLE - GENER HEARING AND VESTIBULAR TAGAMET  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR					
HEARING AND VESTIBULAR TAGAMET  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR					
HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR TAGAMET  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR					
HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR TAGAMET  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR					
HEARING AND VESTIBULAR HEARING AND VESTIBULAR TAGAMET  System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR					
HEARING AND VESTIBULAR  TAGAMET  System Organ Class:  BODY AS A WHOLE - GENER  BODY AS A WHOLE - GENER  HEARING AND VESTIBULAR  HEARING AND VESTIBULAR  HEARING AND VESTIBULAR			<del></del>		
TAGAMET  System Organ Class:  BODY AS A WHOLE - GENER  BODY AS A WHOLE - GENER  HEARING AND VESTIBULAR  HEARING AND VESTIBULAR  HEARING AND VESTIBULAR					
System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR			• • • • • • • • • • • • • • • • • • •	O VESTIBULA	\R
BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR		TAGA	MET		
BODY AS A WHOLE - GENER HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR		•			
HEARING AND VESTIBULAR HEARING AND VESTIBULAR HEARING AND VESTIBULAR			BODY AS A W	HOLE - GENI	ER.
HEARING AND VESTIBULAR HEARING AND VESTIBULAR				·-·	
HEARING AND VESTIBULAR			HEARING ANI	O VESTIBULA	\R
•		•	HEARING ANI	O VESTIBULA	<b>N</b> R
HEARING AND VESTIBULAR			HEARING ANI	O VESTIBULA	<b>AR</b>
			HEARING ANI	O VESTIBULA	AR

AVEAT: The vast majority of reports on which this summary is I pinion or observation of the individual reporter. Cause and effect ports to the Health Canada is raw information and has not been so roportion of suspected adverse reactions are reported to the progry pharmaceutical manufacturers are included in this summary. This your immediate organization. Produced by: Adverse Drug

## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Loratadine as "Interaction drug" All Reports received and entered into database before April 12, 1999

Case report	Drug Age name	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	ı.
RECEIVED TIME APR.13. 11:42AM	HEART RATE HEART RATE GRAVOL System Organ C HEART RATE	CULAR DISORI AND RHYTHM AND RHYTHM Class: AND RHYTHM CULAR DISORI	M DISORDERS M DISORDERS DERS, GENERA		ECG ABNOR TACHYCAR TACHYCAR Interaction - Drug WHO Adverse TACHYCAR ECG ABNOR	DIA VENTRICULAR 3.00 Grams 2 Reaction Term:		
0084437	20 Year(s) CECLOR System Organ ( HEART RATE BODY AS A W BODY AS A W HEART RATE CLARITIN System Organ ( BODY AS A W HEART RATE	AND RHYTHM  WHOLE - GENE WHOLE - GENE AND RHYTHM  Class: WHOLE - GENE AND RHYTHM AND RHYTHM	RAL DISORDEI RAL DISORDEI M DISORDERS RAL DISORDEI M DISORDERS	RS 10 Day(s) RS	PALPITATIO CHEST PAIN SYNCOPE TACHYCARI Interaction -Drug	DIA 10.00 Milligrams 1 Daily e Reaction Term: I DN		

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## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Loratadine as "Interaction drug" All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0086653		3 Year(s)	Female					Recovered with sequelac
0086653	CLARITI	1			03 Week(s)	Interaction -Drug	5.00 Milligrams 1 Daily	
		em Organ Cl	ass:			WHO Adverse	e Reaction Term:	ı
			DISORDERS			SLEEP DISO	RDER	
				SYSTEM DISC	ORDERS	HYPERKINE	ESIA	
	-		DISORDERS			<b>EMOTIONA</b>	L LABILITY	
	INTAL				23 Day(s)	Concomitant	3.00 Dosage form 3 Daily	
0087094		30 Year(s)	Female			<del></del>		Recovered without sequelac
	CLARITI	4				Interaction -Drug	10.00 Milligrams	
	Syst	em Organ Cl	ass:			WHO Adverse	e Reaction Term:	
	CE	TR & PERII	PH NERVOUS	SYSTEM DISC	ORDERS	CRAMPS LE		
	RESPIRATORY SYSTEM DISORDERS					DYSPNOEA	•	
				RAL DISORDE		FATIGUE		
	MU	SCULO-SKE	LETAL SYST	TEM DISORDE		ARTHRALG		
	MINOCIN				06 Day(s)	Interaction -Drug	150.0 Milligrams	
		em Organ Cl					e Reaction Term:	
				TEM DISORDE		ARTHRALG		
				S SYSTEM DIS		CRAMPS LE	EGS	
	BO	DY AS A WE	IOLE - GENE	RAL DISORDE	RS	FATIGUE		• ,
	RES	SPIRATORY	SYSTEM DIS	CORDERS		DYSPNOEA		
0087319		•	Female					Recovered without sequelae
	CLARIT!!					Interaction - Drug	2.00 Dosage form	
		em Organ Cl					e Reaction Term:	
			PH NERVOUS	S SYSTEM DISC	ORDERS	MYOCLONU		
	MANERIX					Interaction -Drug	300.0 Milligrams 2 Daily	
	•	em Organ Cl					e Reaction Term:	
	CE	NTR & PERII	PH NERVOUS	S SYSTEM DISC	ORDERS	MYOCLON	JS	
	CLARITI	٧				Other	As necessary	

## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Lorafadine as "Interaction drug" All Reports received and entered into database before April 12, 1999

Case report	Drug Ag	e Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0087961		Male		Continue of O	Internation Description	10.00 Milligrams	4
ie ie	CLARITIN	01		Continuing on Drug	Interaction - Drug	e Reaction Term:	<b>*</b>
	•	rgan Class:	DAL DISODDE	00	, , , , , , , , , , , , , , , , , , , ,	e reaction term: ED THERAPEUTIC EFFECT	
ŢĬŅĒ		S A WHOLE · GENE	KAL DISONDER	Continuing on Drug	Interaction - Drug	ED MERAFEONC EFFECT	
iπ	PROZAC	rgan Class:		Continuents on Drug	•	e Reaction Term:	
	•	rgan Class. S A WHOLE - GENE	RAL DISORDER	us.		ED THERAPEUTIC EFFECT	
⊅0118505	46 Ye						Unknown
<u></u>	CLARITIN EX	• •		2 Day(s)	Interaction -Drug	1 Dosage form 2 Daily	
ω	•	rgan Class:			WHO Advers	e Reaction Term:	
11		ET, BLEEDING & CL	OTTING DISOR	DERS	HAEMORRI	HAGIC DISORDER	•
••	COUMADIN	•		Continuing on Drug	Interaction - Drug	7 Milligrams Daily	
42AM	System O	rgan Class:			WHO Advers	e Reaction Term:	•
₹	PLATEL	ET,BLEEDING & CL	OTTING DISOR	DERS	HAEMORRI	HAGIC DISORDER	
	ASPIRIN CHIL	DRENS		Continuing on Drug	Concomitant	1 Dosage form 1 Daily	
0119061	43 Ye	ear(s) Male					
	CLARITIN EX	TRA		2 Day(s)	Interaction - Drug	1 Dosage form 2 Daily	
	System O	rgan Class:			WHO Advers	e Reaction Term:	
	SKIN AN	ND APPENDAGES D	SORDERS		RASH HAE	MORRHAGIC	
	COUMADIN			Continuing on Drug	Interaction -Drug	5 Milligrams I Daily	
	System O	rgan Class:				e Reaction Term:	*
	SKIN AN	ID APPENDAGES D	SORDERS		rash haen	MORRHAGIC	
	ASPIRIN CHIL	DRENS		Continuing on Drug	Concomitant	l Dosage form 1 Daily	

Total No. of reports 10

Total No. of reports with fatal outcome

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April 12, 1999

## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine

All Reports received and entered into database before April 12, 1999

Dosage Duration of treatment form	Drug Involvement Dose of drug	Outcome
	Suspected 10.00 Milligrams  WHO Adverse Reaction Term:  VISION ABNORMAL	
S SYSTEM DISORDERS	Suspected 10.00 Milligrams  WHO Adverse Reaction Term:  PARAESTHESIA  DROWSINESS  Concomitant 500.0 Milligrams  Concomitant  Concomitant	Recovered without sequelae
	Suspected 10,00 Milligrams WHO Adverse Reaction Term: SOMNOLENCE Concomitant	
TEM DISORDERS S SYSTEM DISORDERS	Suspected 10.00 Milligrams WHO Adverse Reaction Term: MYALGIA MUSCLE STIFFNESS	
LOTTING DISORDERS	Suspected 10,00 Milligrams  WHO Adverse Reaction Term:  THROMBOCYTOPENIA	
S SYSTEM DISORDERS	Suspected  WHO Adverse Reaction Term:  CONVULSIONS	
is based are submitted by health practitioners and to a fect relationships have not been established in the vasion scientifically or otherwise verified as to cause and engram, consequently this information must not be use	a lesser extent laypersons. Each report represents the standardity of reports submitted. The information contified relationship by Health Canada scientists. Only a few continuous the incidence of subgress reactions. Hence	suspicion, ained in these small April 12, 1999

ogram, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted. This summary contains unpublished data and is provided to you with the understanding that this data will be used only rug. Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

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Drug name	Age	Sex
	42 Year(s)	Female
REAC	TINE	₹)
	VISION DISOR	DERS
	43 Year(s)	Female
REAC	TINE	
	System Organ C	lass:
	<b>PSYCHIATRIC</b>	DISORDERS
ALLB	EE WITH C	
ALLE	RGY INJECTIO	ON
TYLE	NOL	
	29 Year(s)	Female
REAC	TINE	
	System Organ C	lass:
	<b>PSYCHIATRIC</b>	DISORDERS
HYDR	OXYZINE	
		Male
REAC	TINE	
	System Organ C	lass:
	MUSCULO-SK	ELETAL SYSTE
	CENTR & PERI	IPH NERVOUS S
	4 Year(s)	Female
REAC	TINE	
	System Organ C	lass:
	PLATELET, BL	EEDING & CLO
	25 Year(s)	Male
REAC	TINE	
	System Organ C	lass:
		IPH NERVOUS S
	REAC  ALLB ALLE TYLE  REAC  HYDR  REAC	A2 Year(s) REACTINE System Organ C VISION DISOR  43 Year(s) REACTINE System Organ C CENTR & PERI PSYCHIATRIC ALLBEE WITH C ALLERGY INJECTIO TYLENOL  29 Year(s) REACTINE System Organ C PSYCHIATRIC HYDROXYZINE  REACTINE System Organ C MUSCULO-SK CENTR & PERI 4 Year(s) REACTINE System Organ C PLATELET, BL  25 Year(s) REACTINE System Organ C PLATELET, BL  25 Year(s) REACTINE System Organ C

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## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine All Reports received and entered into database before April 12, 1999

Case report	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0086043	REACTIN	53 Year(s)	Female			Suspected	5.00 Milligrams	· · · · · · · · · · · · · · · · · · ·
	-	tem Organ Ci	lass:			WHO Advers	e Reaction Term:	ìŧ
				RAL DISORDE	RS	WITHDRAW	AL SYNDROME	
	CE	NTR & PERI	PH NERVOUS	SYSTEM DISC	ORDERS	WITHDRAW	AL HEADACHE	
	PROVER	A				Concomitant		
0086300		34 Year(s)	Female	<del></del>				Recovered without sequelae
	REACTIN					Suspected	10.00 Milligrams	
		tem Organ C					e Reaction Term:	
				TEM DISORDER		NAUSEA	LLL GLOUDEGLED	
				RAL DISORDE			AL SYNDROME	
				TEM DISORDER	RS	VOMITING	CDEVGED	
	RE	SPIRATORY	SYSTEM DIS	SORDERS		SPUTUM IN	CKEASED	
0086454		•	Female					Recovered without sequelae
	REACTIN	ve				Suspected	10.00 Milligrams 2 Daily	
	Sys	te <mark>m O</mark> rgan C	lass:				e Reaction Term:	
		-	PENDAGES D				INCREASED	
				TEM DISORDE	RS		NORMALITY NOS	
			PENDAGES D			SKIN COLD		
				S SYSTEM DISC			AGGRAVATED	
				RAL DISORDE	RS	CHEST PAIN		
				M DISORDERS		ARRHYTHM	1IA	
	PS	YCHIATRIC	DISORDERS			ANXIETY		
0086660		19 Year(s)	Female					Recovered without sequelae
	REACTIN	<b>NE</b>				Suspected	10.00 Milligrams 1 Daily	
	Sys	tem Organ C	lass:				e Reaction Term:	
	SK	IN AND API	PENDAGES D	ISORDERS		URTICARIA		

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April 12, 1999

#### Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine

All Reports received and entered into database before April 12, 1999

Case report	Drug Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
쒸	55 Year(s	) Male					Recovered without sequelae
0088178	REACTINE				Suspected		Ð
ñ T	System Orga	n Class:			WHO Advers	e Reaction Term:	t .
- -l		SCULAR DISOR	DERS, GENERAL	L	HEART DISC	ORDER	
1 X 1		RY SYSTEM DIS			DYSPNOEA		
٦		WHOLE - GENE		RS	CHEST TIGE	HTNESS OF	
_	ANTIBIOTIC(S)				Concomitant		
D 0 0	ACETYLSALICYI	ACID ENT	: <b>T</b>		Treatment		
<u>.</u>	ATENOLOL	are real barre	•		Treatment		
ນ	HEPARIN				Treatment		
_	NITROGLYCERI	N			Treatment		
. 0088803	30 Year(s						Recovered without sequelae
7 7 0099903	PROZAC	, Temate		05 Day(s)	Suspected	1.00 Dosage form 1 Dai	ly
D D T	System Orga	m Class		• • •	WHO Advers	e Reaction Term:	
		ORY SYSTEM DI	SORDERS		DYSPNOEA		
		TE AND RHYTH			TACHYCAR	RDIA .	
	REACTINE		Digging End	13 Day(s)	Suspected	1.00 Dosage form   Dai	ly
	System Orga	m Class			WHO Advers	e Reaction Term:	
		ORY SYSTEM DI	SORDERS		DYSPNOEA		
		TE AND RHYTH			TACHYCAR	RDIA	
0116754	14 Year(s	s) Female					Unknown
J24701	REACTINE	•			Suspected	120 Milligrams First dos	re
	System Orga	ın Class:			WHO Advers	e Reaction Term:	
		TE AND RHYTH	M DISORDERS		TACHYCAR		
		RIC DISORDERS			SUICIDE AT	FTEMPT	
		ERIPH NERVOU		RDERS	TREMOR		
		RIC DISORDERS			SOMNOLEN		
	<b>PSEUDOEPHEDR</b>	INE HCL		I Day(s)	Concomitant	360 Milligrams First dos	oe e

April 12, 1999

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#### Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine

#### All Reports received and entered into database before April 12, 1999

Case report number	Drug Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116771 E	61	Female					Recovered with sequelac
I⊻	REACTINE			26 Day(s)	Suspected	10 Milligrams Daily	₹/
Ü	System Org	an Class:			WHO Advers	e Reaction Term:	·
	BODY AS	A WHOLE - GENE	RAL DISORDEI	RS	RIGORS		
I I I	VASCULA	R (EXTRACARDIA	AC) DISORDERS	3	FLUSHING		
•	BODY AS	A WHOLE - GENE	RAL DISORDE	RS	MALAISE		
D	LOSEC				Concomitant	20 Milligrams Daily	
APR.	PLENDIL			Continuing on Drug	Concomitant	10 Milligrams Daily	
. 13	PREPULSID				Other	20 Milligrams 2 Daily	
0116801	68 Year	(s) Female					Recovered without sequelae
11	REACTINE				Suspected	10 Milligrams First dose	
	System Org	an Class:			WHO Advers	e Reaction Term:	
429M	HEART R	ATE AND RHYTH	M DISORDERS		PALPITATIO	ON	
3	RENEDIL				Suspected	5 Milligrams Daily	
	System Org	an Class:			WHO Advers	se Reaction Term:	
	HEART R	ATE AND RHYTH	M DISORDERS		PALPITATIO	ON	
	ACETAMINOPH	IEN			Concomitant	1000 Milligrams Daily	
0116802	40 Year	(s) Female					Recovered without sequelae
	REACTINE			1 Day(s)	Suspected	10 Milligrams First dose	
	System Org	gan Class:			WHO Advers	se Reaction Term:	
	RESPIRAT	ORY SYSTEM DIS	SORDERS		BREATHIN	G DIFFICULT	
	CARDIOV	ASCULAR DISORI	DERS, GENERA	L	HYPOTENS	ION	
	SKIN AND	APPENDAGES D	ISORDERS		URTICARIA	ACUTE	

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#### Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine All Reports received and entered into database before April 12, 1999

Case report	Drug Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	ď
0116820	38 Year(s)	Female		4-5 Day(s)	Suspected		Recovered without sequelae	
Š	LAMISIL	llana.		4-3 Day(3)	•	e Reaction Term:	18	
	System Organ C HEART RATE		4 DISORDERS		PALPITATIO			
1 1 1			EM DISORDER	.s	NAUSEA			
1			(C) DISORDER		FLUSHING			
<b>5</b>	REACTINE				Suspected	5 Milligrams		
9	System Organ C	lass:			WHO Adverse	e Reaction Term:		
			EM DISORDER		NAUSEA			
ง			AC) DISORDER	S	FLUSHING			
<u>.</u>	HEART RATE	AND RHYTHI	M DISORDERS		PALPITATIO	ON		
· 011/0/2	11 Year(s)	Male			The second secon	Tak a k	Recovered without sequelae	<del></del> .
0110842	REACTINE			1 Day(s)	Suspected	10 Milligrams Daily		
ž	System Organ (	Class:				e Reaction Term;		
	SKIN AND AP	PENDAGES D	ISORDERS		HIVES			
	BODY AS A W	'HOLE - GENE	RAL DISORDE	RS	CONDITION			
0116847	44 Year(s)	Male	, · <del>2</del> 2 · · · · · · · · · · · · · · · · · ·	<del></del>			Not yet recovered	
	REACTINE			24 Hours(s)	Suspected	10 Milligrams Daily		
	System Organ (	Hass:			WHO Adverse	e Reaction Term:		
	CENTR & PER	IPH NERVOUS	S SYSTEM DISC	ORDERS	CONVULSIO	ONS		
0116849	50 Year(s)	Female				Wales Pro-	Unknown	
43144	REACTINE			2 Year(s)	Suspected	10 Milligrams Daily		
	System Organ (	Class:				e Reaction Term:		
	LIVER AND B	ILIARY SYSTI	EM DISORDERS		LIVER ENLA	ARGEMENT		
	ACETAMINOPHEN			Continuing on Drug	Concomitant			
	<b>AMITRIPTYLINE</b>			Continuing on Drug	Concomitant			
	NIZATIDINE			Continuing on Drug	Concomitant			
	TERFENADINE				Other	,		

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April 12, 1999 Page 5 of 14

## 13 99 됬 ш SURVE ILLANCE TO 18186104817

#### Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine

All Reports received and entered into	database before A	April 12, 1999
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Case report number	Drug A	ge Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
Ĥ <del>011685</del> 0	-	Female					Recovered without sequelae
I	REACTINE				Suspected	10 Milligrams Daily	*/
VED	System (	Organ Class:			WHO Adverse	Reaction Term:	·
Τī	BODY	AS A WHOLE - GENE	RAL DISORDER	RS	EFFICACY, I	LACK OF	
I ME	GASTR	O-INTESTINAL SYST	EM DISORDER	S	ABDOMINA	L PAIN	
	GASTR	O-INTESTINAL SYST	EM DISORDER	S	HYPERSALI		
₽		AS A WHOLE - GENE				AGGRAVATED	
APR.	GASTR	O-INTESTINAL SYST	EM DISORDER	.S	DIARRHOEA	1	
. 13	CORTICOSTI	EROID(S)			Treatment		
•	GAVISCON				Treatment		
<u>☆ 0116883</u>	11.7	rear(s) Male					Unknown
4	REACTINE			3 Week(s)	Suspected	5 Milligrams Daily	
42AM	System (	Organ Class:			WHO Adverse	e Reaction Term:	
3	CENTR	& PERIPH NERVOUS	S SYSTEM DISC	DRDERS	APHASIA M	OTOR	
	PSYCH	IATRIC DISORDERS			LETHARGY		
	PSYCH	IATRIC DISORDERS			SOCIAL DEC	GENERATION	
	SABRIL				Concomitant		
	TEGRETOL				Concomitant		

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# 13 ш DRUG G SURVEILLANCE 613 ቨ

### Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
(1) 0117113		•	Female					Unknown
 M	BRICANY	/L				Suspected	Daily	
	Sys	tem Organ C	lass:			WHO Advers	se Reaction Term:	•
<b></b>	FO	ETAL DISO	RDERS			MISCARRIA	AGE	
TIME	<b>FLONASI</b>	E				Suspected	4 Daily	
	Sys	tem Organ C	lass:			WHO Adver:	se Reaction Term:	
₽	FO	ETAL DISO	RDERS			MISCARRIA	AGE	
PPR.	<b>FLOVEN</b>	r				Suspected		
1 3	Sys	tem Organ C	lass:			WHO Advers	se Reaction Term:	
•	FO:	ETAL DISO	RDERS			MISCARRIA	AGE	
↦	PREPULS	SID				Suspected	2 Dosage form Daily	
<del></del>		tem Organ C				WHO Advers	se Reaction Term:	
42 MA29 M	FO	ETAL DISO	RDERS			MISCARRIA	AGE	- Carrier Control of the Control of
₹	REACTIN	æ				Suspected	3 Weekly	
		tem Organ C				WHO Advers	se Reaction Term:	
	FO	ETAL DISO	RDERS			MISCARRIA	AGE	•
	SALBUVI	ENT				Suspected	400 Micrograms Daily	
		tem Organ C				WHO Advers	se Reaction Term:	
	FO	ETAL DISO	RDERS			MISCARRIA	AGE	
	VITAMIN	C				Suspected	500 Milligrams	
	Sys	tem Organ C	lass:			WHO Advers	se Reaction Term:	
	FO	ETAL DISO	RDERS			MISCARRIA	AGE	

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your jumediate organization. Froduced by: Adverse Drug Reaction Reporting Unit; Bureau of Drug Surveillance, Flierapeutic Products Programme

All Reports received and entered into database before April 12,1999

Dosage form	Duration of treatment	<b>Drug</b> Involvement	Dose of drug	Outcome			
	2 Day(s)	Suspected	5 Milligrams Daily	Not yet recovered			
			se Reaction Term:	·			
RDERS		FACE OEDE					
NERAL DISORDE	RS		LING NON-SPECIFIC				
DISORDERS	DISORDERS  Continuing on Drug		ERYTHEMA				
		Concomitant	1500 Milligrams Daily				
	Continuing on Drug	Concemitant	8 Dosage form Daily				
	Continuing on Drug	Concomitant	325 Milligrams Daily				
	Continuing on Drug	Concomitant	2 Milligrams Daily				
	Continuing on Drug	Concomitant	2 Milligrams Daily				
. 4	The state of the s	A.17	· · · · · · · · · · · · · · · · · · ·	Recovered without sequelae			
	3-4 Day(s)	Suspected	10 Milligrams Daily				
			se Reaction Term:				
US SYSTEM DISC			ADED FEELING				
TIONAL DISORD		HYPOGLYC					
TIONAL DISORD	ERS		GAR DECREASED				
RS		CONFUSION	N				
US SYSTEM DISC		SHAKING					
EIN	Continuing on Drug	Concomitant	1 Dosage form 3 Daily				
	Continuing on Drug	Concomitant					
	Continuing on Drug	Concomitant	Milligrams Daily	•			
	Continuing on Drug	Concomitant					
	Continuing on Drug	Concomitant					
	Continuing on Drug	Concomitant					
	Continuing on Drug	Concomitant	3.75 Milligrams Daily				

ary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, effect relationships have not been established in the vast majority of reports submitted. The information contained in these peen scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by This summary contains unpublished data and is provided to you with the understanding that this data will be used only a Reporting Units Bureausof Drug Surveillance, Therapeutic Products Programme

April 12, 1999

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Case report number	Drug name	Age	Sex
in 7139		70 Year(s)	Male
IVED	REAC	TINE	<b>3</b> )
	•	System Organ C	
TIME		URINARY SYS	
斋		BODY AS A W	
		SKIN AND AP	PENDAGES DI
뀨	ATAS	OL FORTE	
ž	ATRO	VENT	
APR. 13	ENTR	OPHEN	
۳	IMOD	IUM	
<b>₽</b>	TRILA	AFON	
		31 Year(s)	Male
14 <b>8124</b>	REAC	TINE	
3		System Organ C	Hass:
		CENTR & PER	IPH NERVOUS
		METABOLIC A	
		METABOLIC A	
		PSYCHIATRIC	
		CENTR & PER	
		AMINOPHEN '	WITH CODE
		ICASONE	
	= -	OXAMINE	
	INSUL		
	INSUI		
		UM CROMOGI	LYCATE
	ZOPIC	CLONE	

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#### All Reports received and entered into database before April 12, 1999

Case report	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0118284		26 Year(s)	Female					Unknown
<u> </u>	REACTI					Suspected	10 Milligrams Daily	₩
<del>j</del>		stem Organ Cl				WHO Adverse	e Reaction Term:	
<b>=</b>	CI	ENTR & PERI	PH NERVOUS	SYSTEM DISC	ORDERS	HEADACHE		
- - - - - - - - - - - - - - - - - - -	BENADR	YL				Other		
,	HISMAN	AL				Other		
유	SELDAN	E				Other		
0118536	<del></del>	27 Year(s)	Female					Recovered without sequelae
ນ້	REACTI	NE			2 Day(s)	Suspected	40 Milligrams Daily	
	Sy	stem Organ Cl	ass:			WHO Adverse	e Reaction Term:	
<u>1</u>	CI	ENTR & PERI	PH NERVOUS	SYSTEM DISC	ORDERS	CONVULSIO	ONS	
1 1. 42 2 0118702	DILANT	IN .		•	Continuing on Drug	. Concomitant	350 Milligrams Daily	
₹ <del>0118702</del>		•	Female	<u>-</u>				Unknown
	REACTI	NE				Suspected	Daily	
	Sy	stem Organ Cl	ass:			WHO Adverse	e Reaction Term:	
	CO	DLLAGEN DI	SORDERS			LUPUS ERY	THEMATOSUS SYSTE	MIC
	CC	DLLAGEN DI	SORDERS			ANTINUCLI	EAR FACTOR TEST PO	SITIVE
0118890		45 Year(s)	Female					Recovered without sequelae
	ZYRTEC	<b>1</b>			same day	Suspected	10 Milligrams First dose	
	Sy	stem Organ Cl	ass:			WHO Adverse	e Reaction Term:	
		YCHIATRIC				SLEEPINESS	S	

## 13 99 14:47 됬 ш SURVETLLANCE 613 957 TO 18186104817

## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine

All Reports received and entered into database before April 12, 1999

Case report number	Drug A name	ge Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0119202	-	Female					Not yet recovered
0119202	REACTINE			5-6 Day(s)	Suspected	10 Milligrams Daily	*!
	System (	Organ Class:			WHO Adverse	e Reaction Term:	
	PSYCH	ATRIC DISORDERS			PANIC REAC	CTION	
	PSYCH	ATRIC DISORDERS			ANXIETY R	EACTION	
	PSYCH	ATRIC DISORDERS			PARANOID :	REACTION	
	BODY A	AS A WHOLE - GENE	RAL DISORDE	CRS	HOT FLUSH	ES	
	PSYCH	ATRIC DISORDERS			INSOMNIA		
	MARVELON				Concomitant	Daily <sup>,</sup>	
	FLONASE				Other		
	<b>AMITRIPTYL</b>	INE			Treatment	25 Milligrams Daily	
	ATIVAN SUB	<b>L</b>	٠		Trestment	1 Milligrams As necessary	The state of the s
0119494	57 Y	'ear(s) Female		<u> </u>			Recovered without sequelae
	REACTINE			7 Day(s)	Suspected	10 Milligrams Daily	
	System (	Organ Class:			WHO Adverse	e Reaction Term:	
	BODY A	AS A WHOLE - GENE	RAL DISORDE	ERS	CHEST FUL		
	HEART	RATE AND RHYTHM	M DISORDERS			JTTER/ FIBRILLATION	
	HEART	RATE AND RHYTHM	M DISORDERS		TACHYCAR	DIA	
	LOSEC			Centinuing on Drug	Concomitant		
	PREMARIN			Continuing on Drug	Concomitant	0.625 Milligrams Daily	
	<b>PULMICORT</b>			Continuing on Drug	Concomitant		
	VENTOLIN			Continuing on Drug	Concomitant		
	ZOPICLONE			Continuing on Drug	Concomitant	7.5 Milligrams Daily	
	CLARITIN				Other		

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All Reports received and entered into database before April 12, 1999

Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
	1. Desice		16 Million	Recovered without sequelae
	1 Day(s)	Suspected	10 Milligrams Daily	Ť
A DISORDERS		TACHYCAR	se Reaction Term:	
AC) DISORDERS		FLUSHING	WIA	
disorders		PALPITATION	ON	
S SYSTEM DISO	RDERS	BURNING S		
RAL DISORDER		FEVER	,5,15,11,1011	
ERS		FACE OEDE	EMA	
		Treatment		
2	Week(s)	Suspected	5 Milligrams Every oth	er day
		WHO Advers	se Reaction Term:	
RAL DISORDER	S	CHEST PAIR	N	
A DISORDERS		CARDIAC A	ARREST	
M DISORDERS		TORSADE	DE POINTES	
T		Concomitant	650 Milligrams 1 Daily	
		Concomitant		
		Concomitant	25 Milligrams I Daily	
		Concomitant	30 Milligrams 1 Daily	
		Concomitant	2.6 Milligrams 3 Daily	
	2 Day(s)	Suspected	10 Milligrams Daily	Not yet recovered
	2 Day(s)	<b>-</b>	se Reaction Term:	
M DISORDERS		ARRHYTHN		
- DISORDERS		AKKITIAN	WIA NODAL	11.1
	4 Day(s)	Suspected	10 Milligrams Daily	Unknown
		<del>-</del>	se Reaction Term:	
S, FEMALE			STRUAL BLEEDING	
	Continuing on Drug	Concomitant		

is based are submitted by health practitioners and to a lesser extent lappersons. Each report represents the suspicion, ffect relationships have not been established in the vast majority of reports submitted. The information contained in these on scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small ogram, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted. This summary contains unpublished data and is provided to you with the understanding that this data will be used only mug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

April 12, 1999

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REACTINE System Organ Class: HEART RATE AND RHYTHM VASCULAR (EXTRACARDIA HEART RATE AND RHYTHM CENTR & PERIPH NERVOUS BODY AS A WHOLE - GENER URINARY SYSTEM DISORDE BENADRYL  REACTINE System Organ Class: BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT C' ALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM TORGS R  121805  REACTINE System Organ Class: HEART RATE AND RHYTHM TEMPLE System Organ Class: REPRODUCTIVE DISORDER TRIPHASIL	Case report	Drug name	Age	Sex	d
REACTINE  System Organ Class: HEART RATE AND RHYTHM VASCULAR (EXTRACARDIA HEART RATE AND RHYTHM CENTR & PERIPH NERVOUS BODY AS A WHOLE - GENER URINARY SYSTEM DISORDE BENADRYL  REACTINE System Organ Class: BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM 121805  REACTINE System Organ Class: HEART RATE AND RHYTHM Female REACTINE System Organ Class: REPRODUCTIVE DISORDER	1H 9620		38 Year(s)	Female	
HEART RATE AND RHYTHM VASCULAR (EXTRACARDIA HEART RATE AND RHYTHM CENTR & PERIPH NERVOUS BODY AS A WHOLE - GENER URINARY SYSTEM DISORDE BENADRYL  REACTINE System Organ Class: BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CALCOHOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805  REACTINE System Organ Class: HEART RATE AND RHYTHM  Female  REACTINE System Organ Class: REPRODUCTIVE DISORDER		REAC	TINE	*!	
HEART RATE AND RHYTHM CENTR & PERIPH NERVOUS BODY AS A WHOLE - GENER URINARY SYSTEM DISORDE BENADRYL  77 Year(s) Male  REACTINE System Organ Class: BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CTALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805  Female System Organ Class: REACTINE System Organ Class: REPRODUCTIVE DISORDER		• •			
HEART RATE AND RHYTHM CENTR & PERIPH NERVOUS BODY AS A WHOLE - GENER URINARY SYSTEM DISORDE BENADRYL  77 Year(s) Male  REACTINE System Organ Class: BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CTALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805  Female System Organ Class: REACTINE System Organ Class: REPRODUCTIVE DISORDER	Ţ				
CENTR & PERIPH NERVOUS BODY AS A WHOLE - GENER URINARY SYSTEM DISORDE BENADRYL  77 Year(s) Male REACTINE System Organ Class: BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CT ALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM Female System Organ Class: HEART RATE AND RHYTHM  121805  Female System Organ Class: REPRODUCTIVE DISORDER	Ħ		VASCULAR (E	XTRACARDI	AC
BODY AS A WHOLE - GENER URINARY SYSTEM DISORDE BENADRYL  1::0970  77 Year(s)  Male  REACTINE  System Organ Class: BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CALCOHOL  NIFEDIPINE NITRONG SR  121452  89 Year(s)  Male  CETIRIZINE  System Organ Class: HEART RATE AND RHYTHM  System Organ Class: HEART RATE AND RHYTHM  121805  REACTINE  System Organ Class: REPRODUCTIVE DISORDER					
BENADRYL  1:0970  77 Year(s)  Male  REACTINE  System Organ Class:  BODY AS A WHOLE - GENER  HEART RATE AND RHYTHM  HEART RATE AND RHYTHM  ACETYLSALICYLIC ACID ENT CTALCOHOL  ATENOLOL  NIFEDIPINE  NITRONG SR  121452  89 Year(s)  Male  CETIRIZINE  System Organ Class:  HEART RATE AND RHYTHM  121805  REACTINE  System Organ Class:  REPRODUCTIVE DISORDER	<del>P</del>				
BENADRYL  1:0970  77 Year(s)  Male  REACTINE  System Organ Class:  BODY AS A WHOLE - GENER  HEART RATE AND RHYTHM  HEART RATE AND RHYTHM  ACETYLSALICYLIC ACID ENT CTALCOHOL  ATENOLOL  NIFEDIPINE  NITRONG SR  121452  89 Year(s)  Male  CETIRIZINE  System Organ Class:  HEART RATE AND RHYTHM  121805  REACTINE  System Organ Class:  REPRODUCTIVE DISORDER	₹0 •				
REACTINE  System Organ Class:  BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CT ALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM 121805  REACTINE System Organ Class: REPRODUCTIVE DISORDER	13		URINARY SYS	TEM DISORI	DEF
REACTINE  System Organ Class:  BODY AS A WHOLE - GENER  HEART RATE AND RHYTHM  HEART RATE AND RHYTHM  ACETYLSALICYLIC ACID ENT CT  ALCOHOL  ATENOLOL  NIFEDIPINE  NITRONG SR  121452  89 Year(s) Male  CETIRIZINE  System Organ Class:  HEART RATE AND RHYTHM  121805  REACTINE  System Organ Class:  REPRODUCTIVE DISORDER	•	BENA	DRYL		
REACTINE  System Organ Class:  BODY AS A WHOLE - GENER  HEART RATE AND RHYTHM  HEART RATE AND RHYTHM  ACETYLSALICYLIC ACID ENT CT  ALCOHOL  ATENOLOL  NIFEDIPINE  NITRONG SR  121452  89 Year(s) Male  CETIRIZINE  System Organ Class:  HEART RATE AND RHYTHM  121805  REACTINE  System Organ Class:  REPRODUCTIVE DISORDER	12:0970		77 Year(s)		
BODY AS A WHOLE - GENER HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT CTALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805  REACTINE System Organ Class: REPRODUCTIVE DISORDER		REAC	TINE	A. 75. 178.	
HEART RATE AND RHYTHM HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT C' ALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s)  Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM 121805  REACTINE System Organ Class: REPRODUCTIVE DISORDER	₽				
HEART RATE AND RHYTHM ACETYLSALICYLIC ACID ENT C' ALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805  REACTINE System Organ Class: REPRODUCTIVE DISORDER	<del></del>				
ACETYLSALICYLIC ACID ENT C'ALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805  REACTINE System Organ Class: REPRODUCTIVE DISORDER					
ALCOHOL ATENOLOL NIFEDIPINE NITRONG SR  121452  89 Year(s)  Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805  REACTINE System Organ Class: REPRODUCTIVE DISORDER					
ATENOLOL NIFEDIPINE NITRONG SR  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805 Female System Organ Class: REACTINE System Organ Class: REPRODUCTIVE DISORDER		ACET	TYLSALICYLIC	ACID ENT	CT
NIFEDIPINE NITRONG SR  89 Year(s) Male CETIRIZINE System Organ Class: HEART RATE AND RHYTHM  121805 Female System Organ Class: REACTINE System Organ Class: REPRODUCTIVE DISORDER		ALCO	OHOL		
NITRONG SR  89 Year(s) Male  CETIRIZINE  System Organ Class:  HEART RATE AND RHYTHM  121805  Female  System Organ Class:  REACTINE  System Organ Class:  REPRODUCTIVE DISORDER		ATEN	IOLOL		
121452  89 Year(s)  CETIRIZINE  System Organ Class:  HEART RATE AND RHYTHM  121805  Female  REACTINE  System Organ Class:  REPRODUCTIVE DISORDER		NIFE	DIPINE		
CETIRIZINE  System Organ Class: HEART RATE AND RHYTHM  121805 Female  REACTINE  System Organ Class: REPRODUCTIVE DISORDER		NITR	ONG SR		
System Organ Class: HEART RATE AND RHYTHM  121805 Female  REACTINE  System Organ Class: REPRODUCTIVE DISORDER	121452		89 Year(s)	Male	
HEART RATE AND RHYTHM  121805  Female  REACTINE  System Organ Class:  REPRODUCTIVE DISORDER		CETI	RIZINE		
TEACTINE  System Organ Class:  REPRODUCTIVE DISORDER					
REACTINE  System Organ Class:  REPRODUCTIVE DISORDER			HEART RATE	AND RHYTH	IM I
System Organ Class: REPRODUCTIVE DISORDER	121805			Female	
REPRODUCTIVE DISORDER		REAC	CTINE		
			System Organ C	lass:	
TRIPHASIL			REPRODUCTIV	VE DISORDE	RS,
		TRIP	HASIL		

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#### All Reports received and entered into database before April 12, 1999

Case report	t Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0122315	•		Female					Recovered without sequelae	
	BECLOFOR'	LE				Suspected		r r	
	System	Organ Cla	ISS.			WHO Adver.	se Reaction Term:	í	
!	RESPI	RATORY	SYSTEM DISC	ORDERS		THROAT II	URITATION		
<u> </u>			SYSTEM DISC			COUGHING	ì		
•		RATORY	System disc	ORDERS		THROAT S	ORE		
2	REACTINE					Suspected	10 Milligrams Daily		
		Organ Cla					se Reaction Term:		
ט			SYSTEM DISC			THROAT S			
			SYSTEM DISC				RRITATION		
		RATORY	SYSTEM DISC	ORDERS		COUGHING			
•	SEREVENT					Suspected	2 Dosage form 2 Daily		
		Organ Cla			•		se Reaction Term:		
ž			SYSTEM DISC			THROAT S			
			SYSTEM DISC			THROAT IF			
		RATORY	SYSTEM DISC	DRDERS		COUGHING			
	VENTOLIN					Suspected	As necessary		
	•	Organ Cla		an n n n n		WHO Adver.			
			SYSTEM DISC			THROAT SO			
			SYSTEM DISC			THROAT IF	· ·		
			SYSTEM DISC	DRDERS		COUGHING			
	PULMICORT	INHALE	iR.			Other	200 Micrograms 2 Daily		
0122316		Year(s)	Male					Not yet recovered	
	REACTINE					Suspected	10 Milligrams Daily		
	•	Organ Cla				WHO Advers			
			E DISORDERS			PERINEAL			
				AL DISORDE		PAIN			
				AL DISORDE	RS	CONDITION			
		CATION S	ITE DISORDI	ERS		SKIN NODULE			
	LIDEX					Treatment			
			•				+		

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## Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Cetirizine All Reports received and entered into database before April 12, 1999

Case repor 四 number	Drug Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0122320 0122320	17 Year(s)	Male					Unknown
m m	REACTINE				Suspected	10 Milligrams Daily	₩.
	System Organ	ı Class:			WHO Advers	e Reaction Term:	
I H	, ,	BLEEDING & C	LOTTING DISO	RDERS	THROMBOCYTOPENIA		
т́	PLATELET, BLEEDING & CLOTTING DISORDERS				NOSEBLEED		
	-	BLEEDING & C			PETECHIAE	Ę	
뀨	VISION DIS				CONJUNCT	IVAL HAEMORRHAGI	
P 77.	RANITIDINE				Concomitant		
<u>.</u>	CORTICOSTERO	ID(S)			Treatment		
0122322	32 Year(s)	Female					Recovered without sequelae
	CO-TRIMOXAZO	LE			Suspected	1 Dosage form 2 Daily	
1:429M	System Organ	n Class		124 -	WHO Adverse Reaction Term:		17 Table 1 Stage - 1
¥	• •	BLEEDING & C	LOTTING DISO	RDERS	NOSEBLEE	D	
_	FLONASE				Suspected	2 Dosage form Daily	
	System Organ	n Class:			WHO Advers	e Reaction Term:	
		BLEEDING & C	LOTTING DISO	RDERS	NOSEBLEE	D	
	REACTINE			Continuing on Drug	Suspected	10 Milligrams Daily	
	System Organ	n Class:			WHO Advers	e Reaction Term:	
		BLEEDING & C	LOTTING DISO	RDERS	NOSEBLEE	D	
	SUDAFED				Suspected	60 Milligrams 3 Daily	
	System Organ	n Class:			WHO Advers	se Reaction Term:	
		BLEEDING & C	LOTTING DISO	RDERS	NOSEBLEE	D	
0122324	69 Year(s	) Female			·		Not yet recovered
	REACTINE				Suspected	5 Milligrams 2 Daily	
	System Organ	n Class:				se Reaction Term:	
	PSYCHIATRIC DISORDERS		DEPRESSION				
	<b>ATROVENT</b>				Concomitant	Dosage form 3 Daily	
	BECLOFORTE				Concomitant	Dosage form 3 Daily	
	TICLOPIDINE			Continuing on Drug	Concomitant	250 Milligrams 2 Daily	
	VENTOLIN				Concomitant	Dosage form 4 Daily	

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent taypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

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All Reports received and entered into database before April 12, 1999

Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
	l Day(s)	S uspected WHO Advers	10 Milligrams Daily se Reaction Term:	Recovered without sequelac	<del></del>
5		DEPRESSIO	N		
				Unknown	
		Suspected			
		WHO Advers	se Reaction Term:		
ERAL DISORDE	RS	FATIGUE EXTREME			
ERAL DISORDE		CRYING AF	BNORMAL		
S		BAD MOOD	)		
				Recovered without sequelae	
	2 Weck(s)	Suspected	10 Milligrams Daily	The second second	
	, ,	WHO Advers	se Reaction Term:		
<i>R</i>		CONFUSIO	N		
TIONAL DISORD	ERS	HYPONATI	RAEMIA		
		Concomitant			
		Concomitant			
		Concomitant			
		T reasment			

Total No. of reports 43

Total No. of reports with fatal outcome

ry is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, reffect relationships have not been established in the vast majority of reports submitted. The information contained in these een scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted y. This summary contains unpublished data and is provided to you with the understanding that this data will be used only in the contains. The contains the contains that the contains the conta

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Case report	Drug name	Age	Sex				
122325		40 Year(s)	g Male				
Ϋ́E	REAC	TINE	M				
J	Ž.	System Organ C	lass:				
TIME		PSYCHIATRIC					
122326		_	Female				
D	REAC	TINE					
<del>P</del> P X	System Organ Class:						
1 ω	BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER						
<u> </u>		PSYCHIATRIC	DISORDERS				
122495		-	Male				
Ň D	REAC	CTINE					
3		System Organ C	lass:				
PSYCHIATRIC DISORDERS							
	METABOLIC AND NUTRITI						
METHOTRIMEPRAZINE MULTIVITAMINE(S)							
NORMAL SALINE							
		· · · · · · · · · · · · · · · · · · ·					

TOTAL

DCCAVEAT: The vast majority of reports on which this summary is pinion or observation of the individual reporter. Cause and effection of the Health Canada is raw information and has not been proportion of suspected adverse reactions are reported to the proportion of suspected adverse reactions are reported to the proportion of suspected adverse reactions are reported to the proportion of suspected adverse reactions are reported to the proportion of suspected adverse reactions are reported to the proportion of suspected adverse reactions. Produced by: Adverse Drugolius and the proportion of the individual reporter.